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ATTORNEY DOCKET NO. CONFIRMATION NO.

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|--|-------------|----------------------|-------------------------|------------------|--|
| 10/074,272 | 02/14/2002 | Robert K. Yang | 1199-4 | 4926 | |
| 7590 05/16/2005 | | | EXAMINER | | |
| Daniel A. Scola, Jr. HOFFMANN & BARON, LLP 6900 Jericho Turnpike Syosset, NY 11791 | | | LAZOR, MICHELLE A | | |
| | | | ART UNIT | PAPER NUMBER | |
| | | | 1734 | | |
| | | | DATE MAILED: 05/16/2005 | 5 . | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | | |
|--|--|---|---|-------------|--|--|--|
| | | 10/074,272 | YANG ET AL. | | | | |
| Office Action Summary | | Examiner | Art Unit | | | | |
| | | Michelle A. Lazor | 1734 | | | | |
| Period fo | The MAILING DATE of this communication app or Reply | pears on the cover sheet wit | th the correspondence ac | Idress | | | |
| THE I - Exter after - If the - If NO - Failu Any r | ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. In period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a re y within the statutory minimum of thirty vill apply and will expire SIX (6) MON , cause the application to become AB | eply be timely filed ((30) days will be considered time THS from the mailing date of this of ANDONED (35 U.S.C. § 133). | | | | |
| Status | | | | • | | | |
| | Responsive to communication(s) filed on <u>31 M.</u> This action is FINAL . 2b) This Since this application is in condition for allowar closed in accordance with the practice under E | action is non-final. nce except for formal matte | · | e merits is | | | |
| Dispositi | ion of Claims | | | | | | |
| 5)□ 6)⊠ | Claim(s) 54,55,62-78,80,81 and 83-118 is/are 4a) Of the above claim(s) 91-118 is/are withdra Claim(s) is/are allowed. Claim(s) 54,55,62-78,80,81 and 83-90 is/are re Claim(s) is/are objected to. Claim(s) are subject to restriction and/or | ejected. | | | | | |
| Applicati | ion Papers | | • | | | | |
| 9)□ | The specification is objected to by the Examine | r. | | | | | |
| 10)[| ☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| | Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11)[| The oath or declaration is objected to by the Ex | aminer. Note the attached | Office Action or form P | 10-152. | | | |
| Priority u | ınder 35 U.S.C. § 119 | | | | | | |
| a)[| Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priorical application from the International Bureausee the attached detailed Office action for a list | s have been received. s have been received in Aprity documents have been u (PCT Rule 17.2(a)). | oplication No received in this National | Stage | | | |
| Attachmen | | _ | | | | | |
| | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) | | ummary (PTO-413))/Mail Date | | | | |
| 3) 🔲 Inform | mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date | | formal Patent Application (PT) | O-152) | | | |

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 91 – 118 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The original claims are directed generically to drying a film wherein said bottom side of said surface is in substantially uniform contact with a heating source; the new claims are directed to drying said film by applying hot air currents, or in general applying radiant energy, to said bottom side of said surface. However the currently examined claims are directed to applying heat via a water bath to said bottom side of said surface. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. These claims are therefore subject to a species restriction, and are therefore restrictable.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 91 – 118 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claim 54 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear from the claim if a film is first formed and then placed onto a surface having top and bottom sides. According to paragraph 44 (page 13) of the Specification, the film is formed on the surface, not before being placed on the surface. For the purpose of examination, Examiner has assumed the film is formed on the surface as described in the specification.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Claims 54, 55, 63 66, 69-71, 73, 74, 80, 83, 85, 89, and 90 rejected under 35
 U.S.C. 102(b) as being anticipated by Magoon (U.S. Patent No. 4631837).

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Magoon discloses a process comprising combining a water soluble polymer component, such as dietary fiber or polysaccharides inherently contained in fruit pulp, and a polar solvent such as fruit juice/water, to form a matrix with a uniform distribution of said components; forming an ingestible, self-supporting, flexible film or fruit leather when dried, from said matrix (Abstract; column 1, line 41 – column 2, line 8), said film having a uniform thickness greater than about 0.1 mils (column 3, lines 54 - 58), and drying said film by feeding said film onto a surface having top and bottom sides; said bottom side being dried first and being in substantially uniform contact with a water bath at a controlled heated temperature sufficient to dry said film (Figures 1 and 2), wherein a visco-elastic structure is formed. Since the method steps disclosed are identical to those claimed by the Applicant, it is concluded the same results would be obtained, and therefore a non-self-aggregating uniform heterogeneity of said components throughout said film would be produced. In addition, drying of said film begins as soon as the pulp and juice are placed in contact with the heated water, and said polar solvent may have a weight percent of at least 30% (column 4, line 60 - column 5, line 11). Thus Magoon discloses all the limitations of Claims 54, 55, 63 – 66, 69-71, 73, 74, 80, 83, 85, 89, and 90, and anticipates the claimed invention.

Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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7. Claims 62, 67, 68, 72, 78, 81, and 86 – 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magoon as applied in Claim 54 above, in view of Wampler et al. (U.S. Patent No. 5759599).

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Magoon discloses all the limitations of Claim 54, including obtaining a uniform distribution of components wherein a specific amount of each component may be obtained from said film by cutting said film to a predetermined size since the same method steps are disclosed, thus inferring the same results would be obtained; but Magoon does not specifically disclose adding an active component, such as a flavor, to said matrix step; does not disclose said polar solvent to be a combination of water and a polar organic solvent; and does not disclose said water soluble polymer to include a starch. However, Wampler et al. disclose adding flavor, citric acid, considered a polar organic solvent, and starch to fruit leather (column 12, line 63 – column 13, line 6). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to add flavor, citric acid, and starch to fruit leather for enhanced quality. In addition, although Magoon does not specifically disclose dividing said film into dosage forms, it is considered obvious to one of ordinary skill in the art at the time of the invention to divide the film into substantially equal dimensions in order to distribute a measured amount of product for sale.

8. Claims 75 – 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magoon as applied in Claim 54 above.

Magoon does not specifically disclose reducing the weight percent of said polar solvent to about 10% or less; however, one of ordinary skill in the art at the time of the invention would

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know to reduce the amount of solvent in the final product depending on the desired final product qualities, i.e. thickness (column 3, lines 54 - 58 and column 4, lines 18 - 25).

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9. Claim 84 is rejected under 35 U.S.C. 103(a) as being unpatentable over Magoon as applied in Claim 79 above, in view of Kubodera (U.S. Patent No. 4851394).

Magoon discloses all the limitations of Claim 79, but does not disclose said film to have a thickness of about 10 mils or less. However, it is known to produce edible films having a thickness of about 10 mils or less, as shown by Kubodera (column 9, lines 3-9). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to produce a film having a thickness of 10 mils or less since it is well known in the art to produce thin, edible films as disclosed so that the film is minimally, if at all, sensed (column 9, lines 8-9).

Response to Amendment

- 10. Regarding the objection of Claim 87, Examiner withdraws the objection based on the amendment to the claims.
- 11. Regarding the rejection under 35 U.S.C.§112 of Claim 54, Examiner disagrees. It is still unclear from the claim that the film is formed on the surface. The amended claim implies a film is formed and then fed onto a surface. Perhaps more clear language would include "(b) forming a film from said matrix by feeding said matrix onto a surface having top and bottom sides, thereby forming said film".
- 12. Regarding the rejection under 35 U.S.C.§102(b) of Claims 54, 55, 63 66, 69-71, 73, 74, 80, 83, 85, 89, and 90, Examiner disagrees. As discussed above, fruit contains polymeric components that are water soluble, including dietary fiber as discussed in the article "The Benefits of Eating Fibre" by Dr. June V. Engel. Although not specifically discussed in the

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Magoon reference, fruit inherently contains this component, and therefore the Magoon reference anticipates the claimed invention.

In regards to Claim 84, as discussed above, the motivation to combine Magoon with Kubodera is that they both discuss edible films. One in the art looking to Magoon would have been motivated to look to Kubodera when looking to produce a product that would be minimally sensed when consumed.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle A. Lazor whose telephone number is 571-272-1232. The examiner can normally be reached on Wed - Thurs 5:45 - 4:15.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Fiorilla can be reached on 571-272-1187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CHRIS FIORILLA SUPERVISORY PATENT EXAMINER

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